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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/538,134

06/09/2005

Hanbiao Yang

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01/23/2007

GLAXOSMITHKLINE

CORPORATE INTELLECTUAL PROPERTY, MAI B475

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RESEARCH TRIANGLE PARK, NC 27709-3398

EXAMINER

CHU, YONG LIANG

ART UNIT

PAPER NUMBER

1626

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/23/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/538,134	Applicant(s) YANG ET AL.	
	Examiner Yong Chu	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-5, 7-12, 15, 25, 29, 43-45 and 48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2 and 3 is/are allowed.
- 6) ☒ Claim(s) 4, 5, 7, 10-12, 25, 29, 43-45 and 48 is/are rejected.
- 7) ☒ Claim(s) 3, 4, 7-12, 15, 29 and 43 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1, 6, 13-14, 16-24, 26-28, 30-42, and 46-47 have been cancelled by Amendment filed on 5 December 2006. Claim 48 is new. Claims 2-5, 7-12, 15, 25, 29, 43-45, and 48 are pending in the instant application and will be examined on the merits.

Response to Amendment

The Amendment by Applicants' representative Bonnie L. Deppenbrock dated on 5 December 2006 has been entered.

Response to Arguments

Argument over rejection of claims 1, 4-6, 24-28, and 36 under 35 U.S.C. §112(i)

Rejection of claims 1, 4-6, 24-28, and 36 under 35 U.S.C. §112(i) is obviated in view of the deletion of the claims 1 and amended claims 4-6, 24-28, and 36 to reduce the scope of invention enabled by the Specification. Therefore, the rejection over claims 4-6, 24-28, and 36 under 35 U.S.C. §112(i) is withdrawn.

Arguments over rejection of claims 7 and 29 under 35 U.S.C. §112(ii)

The rejection over claim 7 is maintained even after Applicants amended the claim by deleting the term "optionally". As stated in the previous Office action, the term "substituted" render indefinite because of lacking of definition of the "substituted" by in the Specification, not the term "optionally".

The rejection over claim 29 is obviated in view of the amendment of the claim by deleting "N-substituted". Therefore, the rejection over claim 29 under 35 U.S.C. §112(ii) is withdrawn.

Argument over rejection of claims 1, 4, 5, 7-12, 26-28, 36, and 42-44 under 35 U.S.C. §102(b)

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Rejection of claims 1,4,5,7-12, 26-28, 36, and 42-44 under 35 U.S.C. §102(b) is obviated in view of the cancellation of the independent claim 1. The rejection over the claims under 35 U.S.C. §102(b) is moot. Rejection of claims 4,5,7-12, 26-28, 36, and 42-44 under 35 U.S.C. §102(b) is withdrawn in view of the amendment of the claims depending on claim 48, wherein **X** is $-(CH_2)_3$ as amended different from $-(CH_2)_2$ as in the prior art. Therefore, rejection of claims 1,4,5,7-12, 26-28, 36, and 42-44 under 35 U.S.C. §102(b) is withdrawn.

Argument over rejection of claims 1-5, 7-12, 15-22, 24, 28, 36, and 42-44 under 35 U.S.C. §103(a)

Rejection of claims 1-5, 7-12, 15-22, 24, 28, 36, and 42-44 under 35 U.S.C. §103(a) is obviated in view of the cancellation of the independent claim 1. The rejection over the claim 1 is moot and rejection over claims 2-5, 7-12, 15-22, 24, 28, 36, and 42-44 in view of independent new claim 48 under 35 U.S.C. §103(a) is maintained.

Applicant's arguments over rejection of claims 2-5, 7-12, 15-22, 24, 28, 36, and 42-44 now depended on new claim 48 under 35 U.S.C. §103(a) have been fully considered, but are found not persuasive. Applicant's argument on the ground that the Examiner has not established a prima facie case of obviousness because the second reference as online version Wikipedia is not a prior art to the present application due to the publication date is unknown, and the primary prior art alone is not sufficient to support the 103(a) rejection. The Examiner does not agree with Applicant's argument because the publication date of cited 2nd reference of Wikipedia as a cyclopedia is not critical for the rejection. It is used to show a well-known fact to one skilled in the art that furan and pyridine are heterocyclic compounds to support the primary Burkholder prior

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art reference (WO 9426735). Even though Borkholder's compounds are tachykinin receptor antagonists as compared to Applicant's compounds as CCR5 inhibition as antivirals such as HIV, they are both used for pharmaceutical application, which are within the field of the inventor's endeavor. According to MPEP 2112.01

2112.01 [R-3] Composition, Product, and Apparatus Claims

I. PRODUCT AND APPARATUS CLAIMS — WHEN THE STRUCTURE RECITED IN THE REFERENCE IS SUBSTANTIALLY IDENTICAL TO THAT OF THE CLAIMS, CLAIMED PROPERTIES OR FUNCTIONS ARE PRESUMED TO BE INHERENT

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195

To overcome the obviousness rejection, Applicants have to show the evidence that the instantly claimed compounds have unexpected results over the prior art compounds as CCR5 inhibition over instantly claimed utility as antivirals such as HIV, because such antiviral property could be inherent unclaimed property for the prior art compounds. Therefore, the rejection over claims 4, 5, 7, 10-12, 25, 29 and 43-45 under 35 U.S.C. §103(a) is maintained. The rejection of claims 2, 3, 8, 9, and 15 under 35 U.S.C. §103(a) is withdrawn due to the amendment.

Argument over rejection under the obviousness-type double patenting

Applicant's arguments over rejection of claims 1-5, 7-12, 15-22, 24, 28, 36, and 42-44 under the obviousness-type double patenting have been considered. found

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persuasive. Applicant's argument on the ground that the present invention, Ring B is a "4 or 5 membered ring containing a depicted nitrogen" is not obviousness-type double patenting over the cited co-pending U.S. Patent Application No. 2006/0052593 (Serial No. 10/538,145) with Ring B defined as a 6-membered ring is found persuasive. The rejection of claims 1-5, 7-12, 15-22, 24, 28, 36, and 42-44 under the obviousness-type double patenting is withdrawn.

Rejection of new claim 48 under 35 U.S.C. §103(a)

Claim Rejections - 35 USC § 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

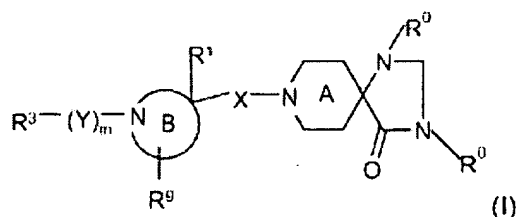
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 48 is rejected under 35 U.S.C. 103 (a) as unpatentable over Burkholder et al., WO 9426735 (publication date 11/24/1994), in view of Wikipedia on heterocyclic

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compound online version where furan and pyridine are exemplified as closely related heterocyclic compounds.

Applicants instantly elected invention in claim 48 teaches compounds of formula



and pharmaceutically acceptable derivatives thereof, wherein

X is $(CH_2)_3$;

Ring A is a saturated, 6-membered monocyclic ring having one ring nitrogen;

Ring B is a saturated 4 or 5 membered ring containing the depicted ring nitrogen;

R^1 is a phenyl or a phenyl substituted with mono- or di- halogen;

Y is $-C(O)-$ or $-C(O)-O-$, and m is 1;

R^3 is H, $-N(R^0)_2$, $-N(R^0)C(O)R^0$, $-CN$, halogen, CF_3 , alkyl optionally substituted by one or more groups selected from R^7 or $-S$ -aryl optionally substituted by $-(CH_2)_{1-6}$ -

$N(R^0)SO_2(R^0)$, alkenyl optionally substituted by one or more groups selected from

R^7 or $-S$ -aryl optionally substituted by $-(CH_2)_{1-6}-N(R^0)SO_2(R^0)$, alkynyl optionally

substituted by one or more groups selected from R^7 or $-S$ -aryl optionally

substituted by $-(CH_2)_{1-6}-N(R^0)SO_2(R^0)$, cycloalkyl or carbocyclyl optionally

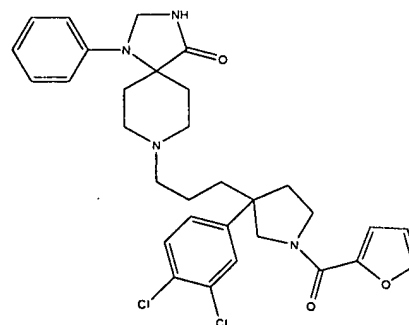
substituted by one or more R^6 , aryl optionally substituted by one or more R^6 ,

heteroaryl optionally substituted by one or more R^6 , or heterocyclyl optionally

substituted by one or more R^6 ;

each R^6 is independently selected from the group consisting of halogen, $-CF_3$, $-OCF_3$,

(I)



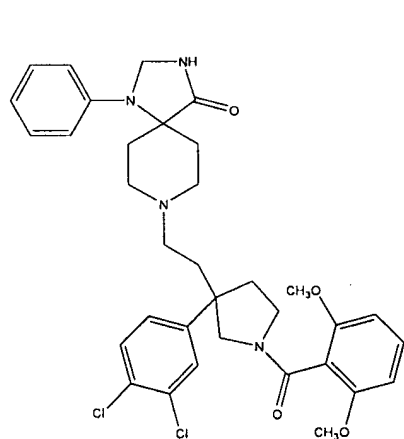
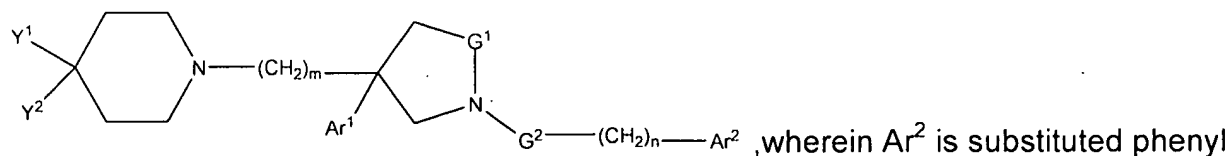
depicted in claim 48 with a elected species of compound

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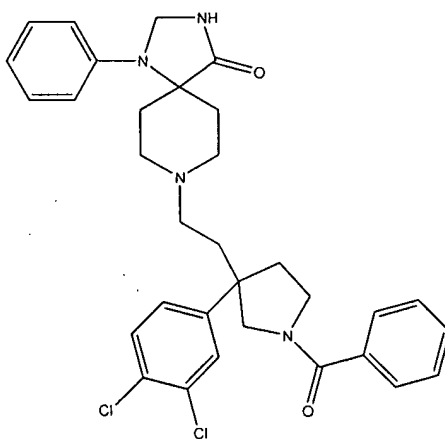
and their pharmaceutical composition. The remaining substituents are defined as in claim 48.

Determination of the scope and content of the prior art (MPEP §2141.01)

Burkholder et al. teach a class of compounds of general chemical formula



and



Burkholder et al.

teach a group of similar compounds of Examples, depicted in the Specification. The anticipating species was delineated *supra*.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The differences between the prior art compounds of Burkholder prior art compounds and the instant application is the alkyl linker **X**, wherein **X** is $-(\text{CH}_2)_2$ for Burkholder compound and $-(\text{CH}_2)_3$ for instantly claimed compounds.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

The instantly claimed compounds would have been obvious over

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Burkholder compounds having **X** as $-(CH_2)_2$ over **X** as $-(CH_2)_3$ for the instantly claimed compounds, because one skilled in the art would have been motivated to prepare homolog of the compounds with **X** as $-(CH_2)_3$ with the expectation of obtaining compounds which could be used in the related compounds or composition for the pharmaceutical application. To those skilled in the chemical art, one homologue is not such an advance over adjacent member of series as requires invention because chemists knowing properties of one member of series would in general know what to expect in adjacent members. *In re Henze*, 85 USPQ 261 (1950). Therefore, the instant claimed compounds would have been suggested to one skilled in the art.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7 recites the limitation " R^1 is aryl or a substituted aryl" in claim 48. There is insufficient antecedent basis for this limitation in the claim. In claim 48, R^1 is a phenyl or a phenyl substituted with mono- or di- halogen. R^1 in claim 7 has a broader definition than R^1 in claim 48, which is depended on.

Claim objection

Claims 4, 7, 10-12, 15, 25, 29, and 43 are objected to because they depend on Claim 48, a subsequent claim. A series of singular dependent claims are permissible in which a dependent claim refers to a preceding claim which, in turn, refers to another preceding claim (see MPEP §601.01(m)).

Claim 5 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 48. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). The definition of R^9 in claim 5 is the same definition as the definition of R^9 in claim 48.

Conclusions

- Claims 4, 5, 7-12, 15, 25, 29, and 43 are objected.
- Claims 4, 5, 7, 10-12, 25, 29, 43-45, and 48 are rejected.
- Claims 2 and 3 are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Chu whose telephone number is 571-272-5759.


The examiner can normally be reached on 7:00 am - 3:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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